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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,202	06/02/2006	Johannes Bartholomaus	512100-2056	3372

20999 7590 11/15/2010
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EXAMINER	
SULLIVAN, DANIELLE D	
ART UNIT	PAPER NUMBER
1617	
MAIL DATE	DELIVERY MODE
11/15/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,202	BARTHOLOMAUS ET AL.	
	Examiner	Art Unit	
	DANIELLE SULLIVAN	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-14 are pending examination. Claims 10-14 were added in the amendment 11/23/2009. Claims 1-4, 6 and 9 were amended in the amendment filed 11/23/2009.

Withdrawn rejections

Applicant's amendments and arguments filed 11/23/2009 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below are herein withdrawn. The rejections under 112 1st and 2nd paragraph over claims 1-6 and 9 have been withdrawn in view of applicant's amendments. Applicant's argument in reference to the inherent properties of the active in claims 7 and 8 have been found persuasive.

Response to Arguments

In view of Applicants amendment to the method steps a new rejection was necessitated. Applicant's arguments with respect to claims 1-9 have been considered but are moot in view of the new ground(s) of rejection.

Applicant argues Nara is related to a dosage form of an enteric capsule and Horstmann was directed to sheet-like administration forms which are completely different. The Examiner is not persuaded by this argument because both Nara and Horstmann are related teach drug formulations that only differ in shape, not composition. In view of *In re Stover*, 56 USPQ 525 (C.C.P.A), it is a matter of choice and not inventions to select any particular shape desired in the finished product.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nara et al. (US 6,245,351) in view of Rupprecht et al. (DE10146251, machine translation)

Applicant's Invention

Applicant claims a process of producing a dosage form in film form comprising at least one active ingredient containing and/or nutrient-containing layer based on hydrophilic polymers crosslinked with at least on polyacrylic derivative, characterized by the steps of a) simultaneously spraying 1) an aqueous solution of the hydrophilic polymers and the active ingredient containing and/or nutrient and 2) an aqueous solution of the polyacrylic acid derivative, where 1) and 2) are mixed after spraying and the hydrophilic polymers are crosslinked by the polyacrylic acid derivatives in situ and, b) removing the water by drying. Claim 2 states the polyacrylic acid derivative is an optionally crosslinked polyacrylic acid. Claim 3 states the hydrophilic polymer is hydroxypropylmethylcellulose, hydroxyethylcellulose and/or methylcellulose. Claim 4 specifies the weigh ratio of hydrophilic polymer to

polyacrylic acid is 5:1 to 5:4. Claim 5 specifies the form comprises at least one active layer, a covering layer and optionally adhesive layer. Claims 7 and 8 are drawn to inherent properties of the formulation. Claim 9 specifies the dosage form is covered by a protective layer. Claim 10 specifies the crosslinked polyacrylic acid is crosslinked with allylsucrose. Claim 11 specifies the hydrophilic polymer is hydroxypropylmethylcellulose. Claim 12 specifies the ratio of the hydrophilic polymers to polyacrylic acid derivatives is from 5:2 to 5:3. Claims 13 and 14 specify an inherent property of the dosage form is that it has a tear strength greater than 40N.

Applicant claims the product made by the process.

Determination of the scope and the content of the prior art

(MPEP 2141.01)

Nara et al. teach a controlled-release composition comprising a drug-containing core coated with a coating composition (abstract). Nara et al. teach a method of producing the drug includes steps wherein the core is sprayed over an inert carrier particle (column 5, lines 54-61). Example 3 discloses a process of preparing morphine hydrochloride solution to spray chill and yield spherical particles (column 9, lines 30-45). The particles were granulated to fine granules and the spray coated solution comprising ethyl cellulose and crosslinked acrylic polymer in the ratio is (70:30). Example 7 discloses a method where in the morphine hydrochloride in formulated into an aqueous solution with hydroxypropylcellulose (column 10, lines 32-63). The resulting mixture was spray coated with a coating solution comprising ethyl cellulose,

hydroxypropylmethyl cellulose and a crosslinked polyacrylic polymer (70:20:10). Crosslinked polymers include those crosslinked with allylsucrose (Carbomer 934P) (column 4, lines 48-54).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

Nara et al. do not teach simultaneous A) spraying of 1) and 2) and mixing the solutions after spraying and B) the step of drying the mixture. Nara et al. do not teach that the dosage is in film form. It is for this reason that Rupprecht et al. is combined.

Rupprecht et al. teach a device for making drug films with at least one spraying device for forming a film forming polymer and drying it (page 1, paragraph 1). The solutions are sprayed simultaneously using two-nozzles systems preferably because they provide uniform distributions of the film-formed components and other components may be crosslinked (page 1, paragraph 14).

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Nara et al. and Rupprecht et al. to further include producing a film form and simultaneous spraying then mixing and with the step of drying the solution. One would have been motivated to use to process of Rupprecht et al. to form a predictable result, a uniform pharmaceutical dosage form.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIELLE SULLIVAN whose telephone number is (571)270-3285. The examiner can normally be reached on 7:30 AM - 5:00 PM Mon-Thur EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun Sajjadi can be reached on (571) 272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Danielle Sullivan
Patent Examiner
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/Joanne Hama/
Primary Examiner, Art Unit 1632